

Remarks

Applicant appreciates the Examiner's consideration of the Amendment filed July 10, 2003 and the subsequent withdrawal of one of the rejections under 35 U.S.C. § 112, second paragraph. Claims 1, 2, 4-12, 14-18, 21-24, 26-35 and 39-43 are pending in the present application. Claims 1-12, 14-18, 21, 22 and 39 stand rejected under 35 U.S.C. § 112, second paragraph. Claims 1-35, 37 and 39-43 stand rejected under 35 U.S.C. § 112, first paragraph. Claims 1, 2, 4-12, 14-18, 21-24, 26-35 and 39-43 stand rejected under 35 U.S.C. § 103. The concerns raised by the Examiner are addressed below as set forth in the Office Action.

I. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-12, 14-18, 21, 22 and 39 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In order to expedite prosecution, Applicant has amended claim 1 to delete the recitation directed to "substituted" dextrin. Accordingly, Applicant respectfully requests withdrawal of this rejection as being moot.

II. Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-35, 37 and 39-43 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. In order to expedite prosecution, Applicant has amended claim 1 to delete the recitation directed to "preventing" the incidence of adhesions as described in the present application. Accordingly, Applicant respectfully requests withdrawal of this rejection as being moot.

III. Claim Rejections Under 35 U.S.C. § 103

A. Claims 22 and 40-43

Claims 22 and 40-43 stand rejected under 35 U.S.C. § 103 as being obvious in view of U.S. Patent No. 5,258,175 to Davies allegedly for the reasons already of record on page 3 of the Office Action mailed May 21, 2002. More specifically, at page 3, the May 21, 2002 Office Action asserts that "it would have been obvious to one of ordinary skill in this art at the time the invention was made having the Davies

patent before him to obtain the claimed composition in view of the closely related structure of the dextrin derivative and similar components present in the composition." Applicant respectfully disagrees with this assertion.

In order to expedite prosecution, Applicant has amended claim 22 to delete the recitation directed to the dextrin "sulphate." Applicant has further amended claim 40 to incorporate the recitations of claim 1 to further clarify the dextrin compositions utilized in the kits of the present invention.

Additionally, in contrast to the dextrin compositions of the present invention, Davies provides a dextrin derivative in which a proportion of the hydroxyl groups in the dextrin have been replaced by strongly acidic groups. See Abstract. Thus, Davies proposes an ionic and substituted dextrin derivative composition. Moreover, Davies states that "[t]he results, summarized in Table 2, demonstrate that paraquat accumulated in the peritoneal cavity against a concentration gradient if dextrin sulphate was present but not with dextrin." Column 6, lines 34-37. Thus, in this case, the treatment of poisoning is effectuated by the dextrin derivative and not the dextrin per se providing evidence of the chemical distinctions between substituted and unsubstituted dextrin which contributes to the ability of one and not the other to interact with paraquat, i.e., paraquat typically binds with high affinity to dextrin sulphate but not to dextrin. As a further example of the chemical distinctions between the two compounds, one skilled in the art would recognize that the substitution of dextrin can lead to a change in the 3-dimensional structure and stereochemistry of the dextrin and impact its metabolism. More specifically, the unsubstituted dextrin of the present invention can be more readily hydrolyzed by amylases than sulphate-substituted dextrin. Thus, the chemical distinctions between a substituted dextrin derivative and an unsubstituted dextrin clearly would be appreciated by one of ordinary skill in the art. Consequently, it would be clear to one of ordinary skill in the art that Davies teaches away from an unsubstituted dextrin composition in favor of a substituted dextrin derivative. Accordingly, Applicant respectfully submits that the substituted dextrin derivative of Davies is not the same as the unsubstituted dextrin of the present invention. Moreover, Davies does not suggest modifying the substituted dextrin derivative to arrive at the dextrin

composition provided by the present invention. Thus, the present invention is not obvious in view of Davies.

B. Claims 1, 2, 4-12, 14-18, 21, 22, 39 and 40-43

Claims 1, 2, 4-12, 14-18, 21, 22, 39 and 40-43 stand rejected under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 5,587,175 to Viegas et al. in view of Davies allegedly for the reasons set forth in the Office Action mailed February 11, 2003. More specifically, at page 7, the February 11, 2003 Office Action asserts that “[o]ne would be motivated to combine the teachings of the Viegas et al. and Davies patents in a rejection of the instant claims since both patents disclose dextrin compositions that have medical applications.” Applicant respectfully disagrees with this assertion.

The case law is clear with respect to obviousness. The cited references, when combined, must teach or suggest *all* the recitations of the claims, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. §2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. §2143.01, citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Moreover, to support combining references, evidence of a suggestion, teaching, or motivation to combine must be **clear and particular**, and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Additionally, the Court of Appeals for the Federal Circuit has further stated that, to support combining or modifying references, there must be **particular** evidence from the prior art as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000).

For reasons set forth above, Applicant respectfully submits that the present invention is not obvious in view of Davies. Applicant further submits that Viegas et al. does not cure the deficiencies of Davies. More specifically, Viegas et al. proposes

that combining a water-soluble film-forming polymer with an ionic polymer optionally in the presence of a latent counter-ion so as to provide an admixture that is "capable of being gelled in situ." Col. 18, line 40. Viegas et al. further states that one of the specific advantages of the invention is "obtained by the incorporation of an ionic polysaccharide in admixture with a film forming, water soluble polymer." Col. 9, lines 25-27).

A "film-forming polymer" typically refers to an aqueous solution that subsequently forms a solid through evaporation, freezing or through a chemical reaction. The proposals in Viegas et al. are directed to formation of a film by a chemical reaction i.e., the presence of an ionic polysaccharide and latent counter-ion. In contrast, the dextrin compositions of the present invention are neither ionic polysaccharides nor water-soluble "film-forming polymers." The claims of the present invention are not directed to processes and/or compositions that are "gelled *in situ*" or to those considered to be "film-forming" in a body cavity. Moreover, there is no direction in Viegas et al. to use anything other than a combination of entities that could undergo a chemical reaction so as to form a gel in situ.

At best, a combination of Davies and Viegas et al. may provide a substituted ionic dextrin derivative that is capable of forming a film in situ. The compositions of the present invention are neither substituted ionic dextrin or derivatives thereof nor do they form a film or gel *in situ* in a body cavity. Instead, the compositions of the present invention remain fluid and do not form a film allowing hydroflotation within the body cavity. Thus, the compositions of the present invention are not obvious in view of the cited references alone or in combination.

C. Claims 23, 24 and 26-35

Claims 23, 24 and 26-35 stand rejected under 35 U.S.C. § 103 as being obvious over Viegas et al. in view of U.S. Patent No. 4,886,789 to Milner allegedly for the reasons already of record on pages 5 and 6 of the Office Action mailed May 21, 2002. More specifically, at page 6, the May 21, 2002 Office Action asserts that "it would have been obvious to one skilled in the art at the time the invention was made to prevent adhesion of organs during the healing process as disclosed in the Viegas patent by applying the dextrin to the peritoneal cavity in view of the recognition in the art, as suggested in the Milner patent, that dextrin does not pass from the abdominal

cavity through the peritoneal membrane and thus does not cause a rapid drop in the osmotic pressure.” Applicant respectfully disagrees with this assertion.

Applicant has amended claim 23 to include recitations that clarify that the dextrin in the method of the present invention is unsubstituted. Additionally, as noted above, Viegas et al. merely proposes film-forming corneal shields or masks. Milner merely proposes a method of peritoneal dialysis using a composition containing an osmotic agent comprising a glucose polymer mixture. *See Abstract.*

As is the case above, the cited references, when combined, do not teach or suggest *all* the recitations of the claims, and there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine reference teachings.

The combination of these two references may, at best, provide a film-forming peritoneal dialysis solution. Thus, Viegas et al., in combination with Milner, fails to provide a method of reducing the incidence of adhesions in a body cavity comprising, among other things, introducing into the body cavity a composition comprising an aqueous formulation further comprising a polysaccharide dextrin in an amount effective to reduce the incidence of adhesions as recited in amended claim 23.

In summary, the compositions of the present invention are effective for reducing the incidence of adhesions. The cited references are directed to compositions and/or methods generally relating to ionic and substituted dextrin derivatives (Davies), an ionic polysaccharide, film-forming polymer (Viegas et al.) and peritoneal dialysis (Milner). None of the cited references acknowledge or address the problem solved by the present invention. More specifically, given the cited references, one of ordinary skill in the art is not provided sufficient teachings to arrive at the unsubstituted dextrin compositions of the present invention.

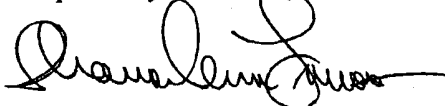
Therefore, Applicant respectfully submits that claims 22 and 40-43 are not obvious in view of Davies, claims 1, 2, 4-12, 14-18, 21, 22, 39 and 40-43 are not obvious in view of Viegas et al. and claims 23, 24 and 26-35 are not obvious in view of the combination of Viegas and Milner. Accordingly, Applicant respectfully requests that these rejections be withdrawn.

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Filed: February 5, 2001
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IV. Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. Any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



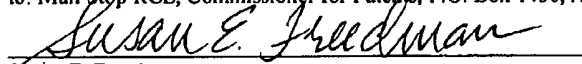
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